DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 12, 2015

Armadillo Biomedical, LLC
% Mr. Greg Holland
Regulatory Consultant
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K142914
Trade/Device Name: DacryoCATH
Regulation Number: Unclassified
Regulation Name: Lacrimal Stents and Intubation Sets
Regulatory Class: Class II
Product Code: OKS
Dated: December 12, 2014
Received: December 15, 2014

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142914/S002

Device Name
DacryoCATH

Indications for Use *(Describe)*
The lacrimal duct catheter is indicated for use during dilation of the obstructed nasolacrimal duct in the following populations:
a. The 2MM catheter is indicated for use during dilation of the obstructed nasolacrimal duct obstruction in patients over 12 months of age and under 30 months of age.
b. The 3 mm catheter is indicated for use during dilation of the obstructed nasolacrimal duct in children over 30 months of age.
c. The 5mm catheter is indicated for use in adults during dilation of a lacrimal duct obstruction or blocked dacryocystorhinostomy ostium as a result of the following: functional or complete nasolacrimal duct obstruction, dacryocystitis, or failed dacryocystorhinostomy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Attachment 1

5. 510(k) Summary

510(k) SUMMARY

510(k) Owner	Armadillo Biomedical LLC 5363 Balboa Blvd., Suite 246 Encino, CA 91316
Contact person	Greg Holland Regulatory Consultant to Armadillo Biomedical LLC Regulatory Specialists, Inc. 3722 Ave. Sausalito Irvine, CA 92606 TEL: 949.262-0411 FAX: 949.552.2821 EMAIL: greg@regulatoryspecialists.com

Date summary was prepared	November 3, 2014
Name of Device	DacroCath
Common Name	Lacrimal duct balloon catheter
Classification Name	Lacrimal Stents and Intubation Sets
Regulation	Pre-Amendment
Class	Unclassified
Panel	Ophthalmic
Product Code	OKS
Predicate	K113508, DacryoCATH

Description

The lacrimal duct catheter is a sterile, single use, non-pyrogenic disposable balloon catheter consisting of a semi-flexible stainless steel hypotube core and nylon balloon tubing. The balloon is designed to inflate to a known diameter and length at the specific pressure. Markings are present 10 and 15 mm proximal to the beginning of the working portion of the balloon, which helps indicate when the balloon is placed correctly in the lacrimal system. The overall length of the catheter is 6 inches (15.24 cm) long. There is an opening on the distal end of the catheter hypotube to accommodate irrigation solutions. The Y-hub on the proximal end of the catheter has a luer port for inflation of the balloon catheter (labeled "inflation" with a red band) and a second luer port for irrigation through the balloon catheter (labeled "irrigation"). The balloon catheter is available in a 2 mm and 3 mm inflated diameter. The 3 mm balloon has a length Of 15 mm and a deflated profile of approximately 1.1 mm. The 2 mm balloon has

a length Of 15 mm and a deflated profile of approximately 1.0 mm. The balloon has a 5 mm inflated diameter and a length of 10 mm. The deflated profile of the 5 mm balloon is approximately 1.2 mm.

Intended Use

The lacrimal duct catheter is intended for use during dilation of the obstructed nasolacrimal duct.

Indications for Use

The lacrimal duct catheter is indicated for use during dilation of the obstructed nasolacrimal duct in the following populations:

a. The 2MM catheter is indicated for use during dilation of the obstructed nasolacrimal duct obstruction in patients over 12 months of age and under 30 months of age.

b. The 3 mm catheter is indicated for use during dilation of the obstructed nasolacrimal duct in children over 30 months of age.

c. The 5mm catheter is indicated for use in adults during dilation of a lacrimal duct obstruction or blocked dacryocystorhinostomy ostium as a result of the following: functional or complete nasolacrimal duct obstruction, dacryocystitis, or failed dacryocystorhinostomy.

Technological Characteristics

The technological characteristics of the DacryoCATH remain unchanged from the predicate K113508. This Special 510(k) is being submitted for a change in patient contact materials and design.

	Original K113508	**New Design**
Balloon Material	PET - polyethylene terephthalate	Nylon 12
Hypotube	304 stainless steel 24 gauge regular wall (OD .022” and ID .010”)	304 Stainless steel 24 gauge thin wall (OD .020” and ID .012”)
Collar	None.	304 stainless steel collar will be welded onto the proximal hypotube

The following non-clinical performance tests were conducted:

Biocompatibility to ISO 10993

- Cytotoxicity
- Sensitization
- Irritation

Product Validations:

- Cycle inflation/deflation time
- Fatigue testing
- Rupture testing
- Tensile testing

Conclusions from non-clinical performance data:

After performing non-clinical performance studies, the data shows that the DacryoCATH is substantially equivalent to the predicate.